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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/477,730	01/05/2000	KOICHI SUGITA	4859-0029-0	9663

7590 03/21/2002
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ARLINGTON, VA 22202

EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 03/21/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/477,730

Applicant(s)

SUGITA ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- ☐ Interview Summary (PTO-413) Paper No(s) _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

The response filed January 7, 2002, paper no.9, has been entered.

Claim 1 is newly amended.

Claims 10-13 are newly added.

Claims 1-13 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1-5 and 7-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a vector comprising a desired gene that is not a selectable marker gene, and a plant hormone signal transduction gene as a selectable marker gene. The claims are also drawn to a vector comprising a desired gene that is not a selectable marker gene, and a selectable marker gene that is a plant hormone signal transduction gene located within a removable DNA element. Additionally, the claims are drawn to a vector comprising a desired gene that is not a selectable marker gene, and a plant hormone synthesis gene together with a plant hormone signal transduction gene as a selectable marker gene.

The specification does not set forth what specific structural features define the claimed vectors comprising plant hormone signal transduction genes as selectable marker genes. In the instant disclosure, applicants describe pIPTCKI-4, a vector comprising a desired gene that is

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not a selectable marker gene, and the cytokinin signal transduction gene CKI1 as a selectable marker gene (pages 27-33 *Example 1*, and *Figure 6*). Applicants also describe pMATCK-1, a vector comprising a desired gene that is not a selectable marker gene and a selectable marker gene that is the cytokinin signal transduction gene CKI1 located within a removable DNA element that is derived from the yeast site-specific recombination system pSR1 (pages 37-42 *Example 3*, and *Figure 14*). Additionally, Applicants describe pIPCK-1, a vector comprising a desired gene that is not a selectable marker gene, and the plant hormone synthesis gene *ipt* together with the plant cytokinin signal transduction gene CKI1 as selectable marker genes (pages 33-35 *Example 2*, and *Figure 8*). Applicants do not describe vectors comprising plant hormone signal transduction genes other than the cytokinin signal transduction gene CKI1. Given the structural and functional diversity of genes that encode proteins involved in plant hormone signal transduction, one skilled in the art could not predict the structure and function of vectors comprising plant hormone signal transduction genes. Structural as well as functional characteristics are required to adequately describe nucleic acids such as a vector.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), where it states:

"The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA ... Accordingly, the specification does not provide a written description of the invention ..."

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed vectors comprising plant hormone signal transduction genes, and given the unpredictability in this art of determining the structure and

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function of vectors comprising plant hormone signal transduction genes, one skilled in the art would not recognize from the disclosure that Applicant was in possession of the claimed invention at the time this application was filed.

Claims 1 and 5 remain rejected, and newly added claims 10-13 are rejected, under 35 U.S.C. 112, first paragraph, for scope of enablement, for the reasons of record set forth in the previous office action.

Claims 1-3 and 9 remain rejected, and newly added claims 10-13 are rejected, under 35 U.S.C. 112, first paragraph, for scope of enablement, for the reasons of record set forth in the previous office action.

Claims 1, 4, and 7-8 remain rejected, and newly added claims 10-13 are rejected, under 35 U.S.C. 112, first paragraph, for scope of enablement, for the reasons of record set forth in the previous office action.

Applicant argues that all of the selectable markers in Walden et al. are antibiotic resistance markers, that antibiotics are not naturally present in plants cells, and that some plants species and cells types have a natural detoxification system against such exogenous chemical substances. Applicant further argues that the instant application is directed to the use of plant hormone signal transduction genes which would be commonly kept in plant species with a high homology because the signal transduction pathway of plants is indispensable for plant growth and differentiation. Applicant argues that the products of these genes are endogenous chemical substances expected to be present in a variety of plant cells, and that the existence of a detoxification mechanism against them would be generally unreasonable.

Applicant's argument has been fully considered but is not persuasive.

The Examiner maintains that the choice of an appropriate selectable marker gene for selecting transgenic plant cells can be unpredictable, whether the selectable marker gene encodes a protein that confers antibiotic resistance or a protein that mediates plant hormone signal transduction. The ability of a protein to function as a selectable marker is limited by the cellular environment, which varies between plant species and cell types. The ability of a protein to function as a selectable marker may be positively or negatively affected by the availability of its substrate and by its own stability in the cellular environment. The Examiner further maintains that the existence of a detoxification mechanism against proteins that mediate plant hormone signal transduction would not only be reasonable, it would be essential. The degradation of endogenous chemical substances is well known to be essential to the maintenance of homeostasis in all biological systems. One of skill in the art would expect cells to have a mechanism to inactivate or degrade proteins that mediate plant hormone signal transduction.

Accordingly, Applicant's argument is not persuasive.

The rejection of claims 1, 4, and 5 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "plant hormone signal transduction gene", is withdrawn in light of the definition in the specification at pages 10-11.

The rejection of claims 2, 3, and 9 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "removable DNA element", is withdrawn in light of the definition in the specification at page 13.

The rejection of claims 4 and 7 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "plant hormone synthesis gene", is withdrawn in light of the definition in the specification at pages 11-12.

The rejection of claim 5 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "cytokinin signal transduction gene", is withdrawn in light of the definition in the specification at pages 10-11.

The rejection of claim 7 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "cytokinin synthesis gene", is withdrawn in light of the definition in the specification at page 12.

The rejection of claim 9 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "site-specific recombination system", is withdrawn in light of the definition in the specification at pages 16-17.

Claim Rejections - 35 USC § 102

The rejection of claims 1, 5, and 6 under 35 U.S.C. 102(b) as being anticipated by Kakimoto et al. is withdrawn in light of the amendment of claim 1 to include the limitation that the desired gene is not a selectable marker gene.

Claim Rejections - 35 USC § 103

Claims 1-9 remain rejected, and newly added claims 10-13 are rejected, under 35 U.S.C. 103(a) as being unpatentable over European Patent No. 0 716 147 (12 June 1996, Applicant's IDS) in view of Kakimoto et al. (8 November 1996, Science, Vol. 274, pages 982-985, Applicant's IDS), for the reasons of record set forth in the previous office action.

Claims 1-9 remain rejected, and newly added claims 10-13 are rejected, under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,965,791 (12 October 1999) in view of Kakimoto et al. (8 November 1996, Science, Vol. 274, pages 982-985, Applicant's IDS), for the reasons of record set forth in the previous office action.

Applicant argues that EP 147 or US 791 taken in combination with Kakimoto et al. fail to suggest the claimed vector, and that the references do not provide any suggestion or motivation for a vector which contains a desired gene which is not a selectable marker gene and a plant hormone signal transduction gene as a selectable marker gene. Applicant further argues that in Kakimoto et al. the desired gene is a plant hormone signal transduction gene which is a selectable marker gene, and that since the Examiner recognizes that both EP 147 or US 791 fail to teach a plant hormone signal transduction gene which is a selectable marker gene, there would be no motivation to construct the claimed vector. Additionally, Applicant argues that the experimental data set forth in the specification are striking evidence of nonobviousness because they demonstrate the unexpected effect of improved selection efficiency using the vector of the claimed invention as compared to the vector described in EP 147 or US 791.

Applicant's arguments have been fully considered but are not persuasive.

The Examiner maintains that Kakimoto et al. teach a vector comprising a desired gene and a plant hormone signal transduction gene as a selectable marker gene. The desired gene of Kakimoto et al. is thus NOT a plant hormone signal transduction gene, but rather any of the additional genes of the Ti plasmid into which the plant hormone signal transduction gene was cloned. Since these additional genes comprise selectable marker genes such as *Amp* and *Htp*, Kakimoto et al. no longer anticipates the claims as amended. The Examiner still maintains, however, that either of EP 147 or US 791 taken in combo with Kakimoto continue to suggest the claimed vectors, since Kakimoto et al. teach a vector comprising a plant hormone signal transduction gene as a selectable marker gene. Furthermore, the Examiner maintains that motivation to combine the references is provided both by the success of EP 147 and US 791 in

using a removable DNA element in a plant transformation vector to enable the removal of a cytokinin synthesis gene selectable marker from transgenic plants, and by the success of Kakimoto et al. in using a plant hormone signal transduction gene as a selectable marker gene in plants. Additionally, the Examiner maintains that because EP 147 and US 791 do not employ a plant hormone signal transduction gene as a selectable marker gene, and because all of the vectors of the claimed invention do employ a plant hormone signal transduction gene as a selectable marker gene, the relevant comparison for nonobviousness would be between the vector of the instant invention and the vector of Kakimoto et al., which does employ a plant hormone signal transduction gene as a selectable marker gene.

Accordingly, Applicant's arguments are not persuasive.

Double Patenting

Claims 1-9 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 5, 6, and 7 of U.S. Patent No. 5,965,791 in view of Kakimoto et al. (8 November 1996, Science, Vol. 274, pages 982-985, Applicant's IDS), for the reasons of record set forth in the previous office action.

Applicant argues that the pending claims are not obvious over US '791 and Kakimoto et al., for the same reasons set forth in the traversal of the rejection made under 103.

Applicant's arguments have been fully considered, but are not persuasive, for the reasons set forth above in response to the traversal of the rejection made under 103.

Accordingly, Applicant's arguments are not persuasive.

Remarks

No claim is allowed.

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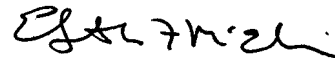
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210.

The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
March 19, 2002


ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1800